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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT

PAPER NUMBER

1636

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Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

### Application No.

09/899,814

### Applicant(s)

DELCARDAYRE ET AL.

### Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-115 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |



### DETAILED ACTION

Claims 1-115 are pending in the instant application.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, 27-43 and 52-53, drawn to a method of making one or more transposable element component *in vitro* (acellular system) with a desired property which is identified *in vitro*, classified in class 435, subclasses 6 and 91.5.
- II. Claims 1-14 and 17-43, drawn to a method of making one or more transposable element component in a *in vitro* (acellular system) with a desired property which is identified in a host cell, classified in class 435, subclasses 29 and 91.5.
- III. Claims 1-16, 27-43 and 52-53, drawn to a method of making one or more transposable element component in a prokaryotic host cell with a desired property which is identified *in vitro*, classified in class 435, subclasses 91.1, 471 and 6.
- IV. Claims 1-14 and 17-43, drawn to a method of making one or more transposable element component in a prokaryotic host cell with a desired property which is identified in a host cell, classified in class 435, subclasses 91.1, 471 and 29.
- V. Claims 1-16, 27-43 and 52-53, drawn to a method of making one or more transposable element component in a eukaryotic host cell with a desired property which is identified *in vitro*, classified in class 435, subclasses 455, 91.1 and 6.
- VI. Claims 1-14 and 17-43, drawn to a method of making one or more transposable element component in a eukaryotic host cell with a desired property which is identified in a host cell, classified in class 435, subclasses 455, 91.1 and 29.



- VII. Claims 1-16, 27-43 and 52-53, drawn to a method of making one or more transposable element component *in silico* with a desired property which is identified *in vitro*, classified in class 435, subclasses 91.5 and 29.
- VIII. Claims 1-14 and 27-43, drawn to a method of making one or more transposable element component *in silico* with a desired property which is identified in a host cell, classified in class 435, subclass 91.5.
- IX. Claims 44-47, drawn to a transposable element with a desired property, classified in class 536, subclass 23.1.
- X. Claims 48-50 and 54-56, drawn to a proteinacious component or functional unit of a transposable element with a desired property, classified in class 530, subclass 350.
- XI. Claims 48 and 51, drawn to a nucleic acid component or functional unit of a transposable element with a desired property, classified in class 536, subclass 23.1.
- XII. Claims 57-60 and 65-67, drawn to a method of using at least one recombinant transposable element or recombinant transposable element component to generate diversity in a population of nucleic acids *in vitro*, classified in class 435, subclass 440.
- XIII. Claims 57-64, drawn to a method of using at least one recombinant transposable element or recombinant transposable element component to generate diversity in a population of nucleic acids in a prokaryotic cell, classified in class 435, subclass 471.



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- XIV. Claims 57-64, drawn to a method of using at least one recombinant transposable element or recombinant transposable element component to generate diversity in a population of nucleic acids in a eukaryotic cell, classified in class 435, subclass 455.
- XV. Claims 68-80, drawn to a method of using transposomes which comprise a library of nucleic acids to generate diversity in a population of acceptor nucleic acids *in vitro*, classified in class 435, subclass 440.
- XVI. Claims 81-102, drawn to a method of identifying a chromosomal locus, which exhibits a desired level of gene expression, classified in class 435, subclass 455.
- XVII. Claims 103-111, drawn to a vector comprising a first inverted repeat, a promoter, a site-specific recombinase recognition site, a polynucleotide encoding a first screenable or selectable marker, a polynucleotide encoding a second screenable or selectable marker and a second inverted repeat, classified in class 435, subclass 320.1.
- XVIII. Claims 112-115, drawn to a vector comprising a transcription regulatory sequence, a 5' splice donor site, a first inverted repeat, a 3' acceptor site, a polynucleotide encoding a transposase, a polynucleotide encoding a selectable marker, and a second inverted repeat, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,



different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation including the making of one or more transposable element component *in vitro* (Groups I-II), in a prokaryotic host cell (Groups III-IV), in a eukaryotic host cell (Groups V-VI) or *in silico* (Groups VII-VIII) and different outcomes based upon the structural/functional properties necessary for the desired property identified *in vitro* (Groups I, III, V and VII) or in a host cell (Groups II, IV, VI and VIII).

Claims 1, 14 and 52 link(s) inventions of Groups I-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 14 and 52. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Group X and Group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically, biologically and functionally distinct from



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each other and thus one does not render the other obvious. The product of each group is not needed to produce the product of the other group.

Claim 48 link(s) inventions of Groups X-XI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 48. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups I-VIII and Group IX are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another materially different process such as error-prone PCR.

Inventions of Groups I-VIII and Groups X-XI are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1)



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that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made by another materially different process such as error-prone PCR. For Group X, this process can be followed by *in vitro* transcription/translation.

Inventions of Groups XII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation based upon the method steps used to generate nucleotide sequence diversity in a population of nucleic acids *in vitro* (Group XII), in a prokaryotic cell (Group XIII) or in a eukaryotic cell (Group XIV).

Claim 57 link(s) inventions of Groups XII-XIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 57. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.



*In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions of Groups I-VIII and Groups XII-XIV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-VIII comprise steps which are not required for or present in the methods of Groups XII-XIV: providing a population of polynucleotide segments comprising at least one transposable element or sub-portion of a transposable element, recombining, and identifying a transposable element component with any desired property (Groups I-VIII) or contacting at least one recombinant transposable element or transposable element component with a plurality of subject nucleic acids under conditions permissive for transposition (Groups XII-XIV). The end results of the methods are different: producing one or more transposable element component with a desired property (Groups I-VIII) or transposing a transposable element or transposable element component into a population of nucleic acids to generate diversity (Groups XII-XIV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups I-VIII and Group XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-VIII comprise steps which are not required for or present in the methods of Group XV: providing a population of polynucleotide segments comprising at least one transposable element or sub-portion of a transposable element, recombining, and identifying a transposable element component with any desired property (Groups I-VIII) or providing a plurality of transposomes,



comprising a library of donor nucleic acids, and a population of acceptor nucleic acids and recombining the donor and acceptor nucleic acids *in vitro* (Group XV). The end results of the methods are different: producing one or more transposable element component with a desired property (Groups I-VIII) or generating recombinant molecules from donor and acceptor nucleic acids (Group XV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups I-VIII and Group XVI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I-VIII comprise steps which are not required for or present in the methods of Group XVI: providing a population of polynucleotide segments comprising at least one transposable element or sub-portion of a transposable element, recombining, and identifying a transposable element component with any desired property (Groups I-VIII) or transfecting a plurality of host cells with a vector, identifying at least one cell that expresses a sufficient level of at least one selectable marker carried by the vector, and identifying at least one host cell expressing at least one screenable or selectable marker, carried by the vector, at a desired level (Group XVI). The end results of the methods are different: producing one or more transposable element component with a desired property (Groups I-VIII) or identifying a chromosomal locus which exhibits a desired level of gene expression (Group XVI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.



Inventions of Groups I-VIII and Group XVII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The vector of Group XVII is not used in the methods of Groups I-VIII. The operation, function and effects of the vector of Group XVII (i.e. to express a first and second screenable or selectable marker) are completely different and distinct from the operation, function and effects of the methods of Groups I-VIII which produce one or more transposable element component. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups I-VIII and Group XVIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The vector of Group XVIII is not used in the methods of Groups I-VIII. The operation, function and effects of the vector of Group XVIII (i.e. to express a screenable or selectable marker) are completely different and distinct from the operation, function and effects of the methods of Groups I-VIII which produce one or more transposable element component. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The transposable element of Group IX, the transposable element components of Groups X-XI, and the vectors of Groups XVII-XVIII are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need from the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.



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Inventions of Group IX and Groups XII-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the identification of chromosomal loci which exhibit a desired level of gene expression.

The inventions of Group IX and Group XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The transposable element is not used in the methods of Group XV. The operation, function and effects of the transposable element of Group IX (e.g. to insert into a polynucleotide) are completely different and distinct from the operation, function and effects of the methods of Group XV which uses transposomes comprising a transposase and a donor nucleic acid to generate diversity in a population of acceptor nucleic acids. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group IX and Groups XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the mutagenesis of a host cell genome.



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Inventions of Group X and Groups XII-XIV are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the formation of transposomes.

Inventions of Group XI and Groups XII-XIV are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as the use of polynucleotide repeats in the construction of a vector molecule.

The inventions of Group X and Group XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The transposable element is not used in the methods of Group XV. The operation, function and effects of the transposable element component of Group X (e.g. transposase) are completely different and distinct from the operation, function and effects of the methods of Group XV which uses transposomes comprising a transposase and a donor nucleic acid to generate diversity in a population of acceptor nucleic acids. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.



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The inventions of Group XI and Group XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The transposable element is not used in the methods of Group XV. The operation, function and effects of the transposable element component of Group XI (e.g. polynucleotide repeats) are completely different and distinct from the operation, function and effects of the methods of Group XV which uses transposomes comprising a transposase and a donor nucleic acid to generate diversity in a population of acceptor nucleic acids. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups XII-XIV and Group XV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of the groups comprise steps which are not required for or present in the methods of the other groups: contacting at least one recombinant transposable element or transposable element component with a plurality of subject nucleic acids under conditions permissive for transposition (Groups XII-XIV) and using transposomes comprising a transposase and a donor nucleic acid to generate diversity in a population of acceptor nucleic acids (Group XV). The end result of the methods are different: transposing a transposable element or transposable element component into a population of nucleic acids to generate diversity (Groups XII-XIV) or generating recombinant molecules from donor and acceptor nucleic acids (Group XV). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups XII-XIV and Group XVI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of the



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groups comprise steps which are not required for or present in the methods of the other groups: contacting at least one recombinant transposable element or transposable element component with a plurality of subject nucleic acids under conditions permissive for transposition (Groups XII-XIV) and transfecting a plurality of host cells with a vector, identifying at least one cell that expresses a sufficient level of at least one selectable marker carried by the vector, and identifying at least one host cell expressing at least one screenable or selectable marker, carried by the vector, at a desired level (Group XVI). The end results of the methods are different: transposing a transposable element or transposable element component into a population of nucleic acids to generate diversity (Groups XII-XIV) or identifying a chromosomal locus which exhibits a desired level of gene expression (Group XVI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups XII-XIV and Group XVII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The vector of Group XVII is not used in the methods of Groups XII-XIV. The operation, function and effects of the vector of Group XVII (i.e. to express a first and second screenable or selectable marker) are completely different and distinct from the operation, function and effects of the methods of Groups XII-XIV which generate diversity in a population of nucleic acids by the transposition of a transposable element or transposable element component. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Groups XII-XIV and Group XVIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The vector



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of Group XVIII is not used in the methods of Groups XII-XIV. The operation, function and effects of the vector of Group XVIII (i.e. to express a screenable or selectable marker) are completely different and distinct from the operation, function and effects of the methods of Groups XII-XIV which generate diversity in a population of nucleic acids by the transposition of a transposable element or transposable element component. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group XVI and Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group X as claimed is not produced or used by the methods of Group XVI.

Inventions of Group XVI and Group XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group XI as claimed is not produced or used by the methods of Group XVI.

Inventions of Groups XV and Group XVI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of the groups comprise steps which are not required for or present in the methods of the other groups: using transposomes comprising a transposase and a donor nucleic acid to generate diversity in a population of acceptor nucleic acids (Group XV) and transfecting a plurality of host cells with a vector, identifying at least one cell that expresses a sufficient level of at least one selectable



marker carried by the vector, and identifying at least one host cell expressing at least one screenable or selectable marker, carried by the vector, at a desired level (Group XVI). The end results of the methods are different: generating recombinant molecules from donor and acceptor nucleic acids (Group XV) or identifying a chromosomal locus which exhibits a desired level of gene expression (Group XVI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group XV and Group XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group XVII as claimed is not produced or used by the methods of Group XV.

Inventions of Group XV and Group XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group XVIII as claimed is not produced or used by the methods of Group XV.

Inventions XVII and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP



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§ 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as mutagenesis of the genome of a host cell.

Inventions of Group XVI and Group XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the product of Group XVIII as claimed is not produced or used by the methods of Group XVI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

For groups with the same classification, different searches of the non-patent literature are required (e.g. *in vivo* vs. *in vitro* screening assays). For this reason and the reasons given above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found



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allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Dunston  
Examiner  
Art Unit 1636

jad

  
GERRY LEFFERS  
PRIMARY EXAMINER